# Herbal Supplements: Considerations for the Athletic Trainer

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**Objective:** To examine common herbal supplements, explore potential risks associated with herbal use, and provide recommendations to the athletic trainer regarding patient care issues.

**Data Sources:** We searched MEDLINE, SPORT Discus, CINAHL, and Academic Search Elite databases 1990–2000 using the key words *herbals*, *regulation*, *supplements*, *toxicity*, and *adulteration*.

**Data Synthesis:** The use of herbal products continues to grow. While the origins of some medications and herbal supplements are similar, clinical testing and understanding of most herbal remedies is lacking. Some herbal products may prove

useful in an athletic setting; however, current United States Food and Drug Administration (FDA) regulations do not ensure safe and effective products. A descriptive review focusing on specific considerations for the athletic trainer is provided.

Conclusions/Recommendations: Despite their increasing tendency to seek natural therapies, athletes need to be aware that "natural" does not equal "safe." Athletes are entitled to know that most herbs are not proven safe or effective under current FDA standards. The athletic trainer must be able to provide honest, unbiased information when educating athletes regarding herbal supplements.

Key Words: herbals, botanicals, toxicity, adulteration, regulation

Recent increases in the availability and popularity of herbal supplements and complementary health care products have created an environment of hyperbole and misinformation for patients and health care providers alike. Athletic trainers and other health care professionals must be able to distinguish fact from fiction and direct their patients to appropriate sources when trying to determine the efficacy and potential dangers of these products. Reports indicate that Americans spend in excess of \$12 billion annually on vitamins, minerals, herbals, sports supplements, and specialty supplements.

The prevalence of herbal use is largely unstudied.<sup>2–4</sup> It is estimated that 33% of patients have used at least 1 unconventional treatment in the past year.3 Eisenberg et al3 defined unconventional treatments as medical interventions not taught widely at United States (US) medical schools or generally available at US hospitals; examples include acupuncture, chiropractic, and massage therapy. In another study, Eliason et al<sup>5</sup> found that 52% of patients have taken 1 or more dietary supplements during the past year, and that the media is their primary source of information about the supplements. Compounding this increase in availability and use are government regulations that limit the Food and Drug Administration's (FDA) ability to regulate any product labeled as a supplement. The 1994 Dietary Supplement and Health Education Act (DSHEA) allows companies to promote supplements with claims of improved "function and health" as long as they make no claims to affect disease.6

Athletes demonstrate a greater willingness to use supplement products when compared with their nonathlete counterparts.<sup>7</sup> The athletic trainer is often called upon to serve as an educa-

tional resource for athletes wishing to learn more about herbal supplements. Herbal products are vigorously marketed to both competitive and recreational athletes with claims of performance gains and improved health and wellness. This review examines the regulation of herbal supplements, explores potential risks associated with herbal use, and provides recommendations to the athletic trainer regarding patient care issues.

#### **REGULATION**

# Food and Drug Administration

The regulation of herbal products has proven to be a confusing blend of public safety issues, varied international guidelines, advertising hyperbole, and partisan politics. In the US, the regulation of drugs, food, and cosmetics is the job of the FDA, which helps assure the public that drugs are safe and effective and have been subject to scientific scrutiny. In 1962, the FDA required that all drugs be evaluated for safety and efficacy.8 To avoid the burden of proof associated with FDA approval, herbal manufacturers began to label herbs as "foods" and sell them in health food stores. The FDA maintains a list of products "Generally Recognized as Safe" (GRAS). Appoximately 250 herbs appear on this list, but these are herbs used for food flavoring and not for medicinal purposes. Currently, only a handful of herbs have been shown safe and effective based on a 1990 FDA review of over-thecounter drugs (Table 1).9

It is estimated that more than 1400 herbs are commonly sold and promoted for medicinal uses worldwide. 1,2,4 Historically,

Table 1. Common Herbs With FDA Approval<sup>2</sup>

Herbs*	Approved Use	Recommended Dosage <sup>10</sup>	Adverse Effects/Warnings/Comments
Aloe Aloe barbadensis (fresh gel, dried juice)	Laxative	20-30 mg/d Anhydrous aloin	Loss of electrolytes with chronic use; contra- indicated if gastrointestinal obstruction is present; do not use if pregnant or lactating.
Capsicum or cayenne pepper Capsicum spp. (fruits)	Topical analgesic/counter irritant	50 mg Capsaicin in 100 mg neu- tral base; use beyond 2 days is not recommended	Avoid touching eyes or mucous membranes after applying product.
Cascara  Rhamnus purshiana (dried bark)	Laxative	20-30 mg Tablet cascaroside/d	Loss of electrolytes with chronic use; contra- indicated if gastrointestinal obstruction is present; do not use if pregnant or lactating.
Psyllium  Plantago psyllium, P. ovata, P. spp (seed)	Laxative	Varies; 12–40 g/d; 1–3 tea- spoons; 5–15 g soaked in wa- ter, taken with ample liquid (1– 2 glasses of water)	Contraindicated if gastrointestinal obstruction is present; allergic reactions (rare).
Senna <i>Cassia</i> spp. (leaflets)	Laxative	Often taken as an infusion or tea; 0.5–2 g steeped in hot water for 10 minutes	Diarrhea, nausea; avoid chronic use.
Slippery elm <i>Ulmus fulva</i> (inner bark)	Oral demulcent/agent that forms a soothing, pro- tective film on a mucous membrane surface	No specified dosage	No adverse warnings; available in throat lozenges and teas.
Witch hazel  Hamamelis virginiana (leaves, bark)	Astringent	External – diluted 1:3 with water or 1:3 as steam distillate; ointment/gel: 5 g witch hazel in 100 g ointment base	Stomach irritation, liver damage if taken internally (rare).

<sup>\*</sup>Common name, scientific name, (parts of plant used).

US manufacturers have had little incentive to seek FDA approval due to the costs associated with drug research. In turn, herbs reviewed by the FDA have only been examined within a very narrow definition of medicinal actions. This left the public largely unaware of which products were safe, effective, or both safe and effective.

In 1993, the FDA distributed an advance notice of proposed rule making that addressed the herbal and supplement industry. The report discussed instances of herb-related deaths and concerns about toxicities. The consensus in Washington was that stricter regulation was on the way. What resulted was an unanticipated public and political backlash from consumers who thought that their access to herbals and supplements would be taken away. At the urging of the supplement industry, Congress was deluged with millions of letters and faxes. The result was DSHEA, a political compromise that has limited the FDA's influence on herbal products.

This legislation allows herbal products to be sold without any testing for efficacy. Companies cannot make claims on an herb's ability to cure a disease, but they may make claims about how a supplement affects the "structure" and "function" of the body. This nebulous language has not helped to clear the confusion surrounding the herbal industry. For example, an herb could not be claimed to cure inflammation but could be claimed to promote healthy joints (structure and function). Manufacturers can make structure and function claims as long as they provide a disclaimer stating that their products have not been reviewed by the FDA and are not intended to be used as drugs.<sup>6</sup> Under the current legislation, supplement makers do not have to prove a product is safe; the FDA has the burden of proving a product is unsafe. The FDA can only take action if a product is found to present a significant or unreasonable risk of illness or injury. Further confounding the herbal landscape are studies that show consumers tend to believe that products sold in a pill form have been reviewed for safety by the FDA, despite required label disclaimers.<sup>11,12</sup>

#### International Considerations

Given the limited number of herbs with FDA approval, considerable information on the use and dosage of herbals comes from European guidelines.<sup>4</sup> These guidelines vary considerably from one country to the next and often rely on the historical use of a product. Substances are often accepted under the doctrine of reasonable certainty because they have a long history of use. This philosophy is similar to the World Health Organization's Guidelines for the Assessment of Herbal Medicines, which state that a substance's historical use is a valid way to document safety and efficacy in the absence of scientific evidence to the contrary.<sup>13</sup> A long history of use may allow for safety information to be gathered; however, it may do little to assess efficacy.

The most often cited European guidelines are those of the German Commission E. Beginning in 1978, the German Commission E has reviewed clinical literature (including clinical trials and case studies) on more than 1400 herbal drugs.<sup>2,4</sup> The commission has produced more than 300 monographs on common herbal remedies. However, these monographs must be used with caution given their reliance on historical bibliographic information that may or may not include data gathered from clinical trials.

Athletic trainers must also be aware of the availability of Chinese herbal preparations and Ayurvedic herbal products. Ayurvedic herbs are used in the Ayurveda medical system that is common in India. Currently, about 300 herbs are used in general practice in traditional Chinese medicine. Often these herbs are sold in preparations that contain multiple herbs. For example, Chinese black balls contain up to 20 different herbs

and are used to treat everything from arthritis to asthma.<sup>14</sup> Both Chinese and Ayurvedic products are largely unregulated, and some do not list ingredients in English. The concerns for athletes range from positive drug testing to the risk of toxicity due to unknown ingredients.

#### **RISK FACTORS**

# **Concentration and Purity**

The risks associated with the use of herbal remedies and supplements can range from minor skin irritations to death. Determining the safety and efficacy of herbal products continues to be difficult because the FDA, herbal supplement manufacturers, and herbal experts disagree on how to interpret the varying evidence available for many types of herbal remedies. 15 Owing to the limited regulation of herbs, patients are often unable to tell how much of the herb or which part of the herb is contained within a given product. Both the scientific literature and the media have reported concerns with herbal products. In 1995, Consumer Reports<sup>1</sup> tested 10 brands of ginseng and found substantial variations in concentration among brands. In March 1998, the Good Housekeeping Institute tested 9 brands of St. John's wort and found a significant variation in the amount of active ingredient. The Los Angeles Times also tested St. John's wort in 1998 and found that 7 of the 10 brands tested were low in the amount of purported active ingredient. An herb's ability to create a physiologic response depends upon the availability of a specific chemical constituent. The variability of these active ingredients is of concern because the most profound risks of herbal product use are toxicity and adverse reactions, herb-drug interactions, and adulteration of herbal products.

#### **Toxicities and Adverse Reactions**

Numerous cases of toxicity have been linked to the use of herbal products. 16-47 The resulting problems range from minor adverse reactions to serious physical disabilities and death. Adverse reactions have been reported in athletic training settings. Myers et al<sup>47</sup> reported syncope and atypical chest pain in an intercollegiate wrestler after ingestion of an over-thecounter metabolic stimulant containing Chinese herbal extracts. This particular stimulant (Ripped Fuel, Twinlab Inc, Ronkonkoma, NY) contained ma huang (ephedrine) and caffeine. The stimulant effects were compounded by the athlete's aggressive weight-loss techniques. Winterstein (unpublished data, 2000) described a 19-year-old female soccer player with an episode of syncope and tachycardia after ingestion of an over-the-counter stimulant containing ma huang, guarana, and caffeine. This athlete had also been severely restricting calories to lose weight. These cases illustrate a common problem: athletes taking products that are marketed as "metabolism boosters" that contain "natural" herbal ingredients.

The herb ma huang and all ephedrine alkaloids have received considerable attention from the FDA. More than 15 deaths have been attributed to the use of ephedrine alkaloid products.<sup>47</sup> In 1996, the FDA issued a warning to consumers to avoid nutritional supplements containing ephedrine.<sup>48</sup> In 1997, the FDA proposed the use of warning labels addressing the adverse effects of ephedrine, banning products containing more than 8 mg per serving, and eliminating products containing combinations of ephedrine and caffeine.<sup>49</sup> The FDA

received 14 775 public comments in response to the 1997 ephedrine alkaloids proposal. The Center for Food Safety and Applied Nutrition and the FDA's Center for Drug Evaluation and Research have examined hundreds of reports from consumers who have experienced adverse effects from supplements containing ephedrine. Despite the volume of adverse reactions, the FDA has yet to impose the 1997 proposed rule changes and continues to meet resistance and political pressure from herbal manufacturers.<sup>50</sup>

In addition to recent concerns over products containing ma huang and ephedrine alkaloids, the FDA has recently made public additional concerns over botanical products containing aristolochic acid. Aristolochic acid is a known carcinogen and nephrotoxin; side effects include interstitial renal fibrosis and renal failure. A recent FDA report<sup>51</sup> identified 76 botanicals known or suspected of containing aristolochic acid and 92 botanicals believed adulterated with aristolochic acid. Products containing a large amount of this substance may produce rapid-onset toxicity. However, the effects of long-term use are unknown. The first indication of adverse effects may be irreversible, such as renal failure.<sup>51</sup>

The toxicity and adverse effects of some common herbs that athletes may come in contact with or may already be using are outlined in Table 2. These are categorized as stimulants or energy boosters, weight-control agents, pain-control (ie, analgesics) and wound-healing agents, anti-inflammatories, anti-depressants, and sleep aids.

Some herbal drugs on the market have been found to be relatively safe and free of serious adverse effects when taken in specific dosages (Table 3).<sup>4</sup> These herbs have undergone clinical trials, have been reviewed by German Commission E, or have a history of safe consumption.

Despite safety claims, patients and health care providers should be aware that abuse of dosages and problems with adulteration may render an otherwise safe herbal product dangerous. Ginseng, although considered by many sources to be relatively safe, had a high incidence of adverse effects in a 2-year study by Siegel. <sup>56</sup> The long-term use of ginseng has been associated with central nervous system excitation and arousal. <sup>57</sup> The long-term effects have been labeled ginseng abuse syndrome. <sup>56,57</sup>

#### **Herb-Drug Interactions**

Patients often neglect to mention herbs when asked by their health care providers about medications taken on a regular basis because they (1) assume that herbs are natural,<sup>3</sup> (2) are embarrassed by the reason they are taking the herb, or (3) feel their physician will not approve of their herbal use.<sup>52,69</sup> However, not informing health care providers about herbal use places patients at risk because of the possible interactions between drugs and herbs (Table 4). Owing to a lack of research showing which herb-drug combinations athletes are likely to consume, we have included examples from the literature of over-the-counter and prescription drugs that athletes may come in contact with or may already be using. The known effects of using prescription drugs and herbs in combination are that herbs can "mimic, magnify, or oppose the effect of the drugs."69,70 Athletic trainers need to be sensitive, form a trusting relationship with athletes, and ask about the possible use of herbal products in a nonthreatening manner.

# **Product Adulteration**

Despite attempts to improve manufacturing processes, reports on product adulteration, contamination, or both are com-

Table 2. Toxicity and Adverse Effects of Common Herbs

Herb Name	Common Use	Toxicity/Adverse Effects	Supplements Containing Suspect Herbs
Stimulants/energy boosters			
Asian ginseng <sup>1,52</sup>	Increase energy, improve mood, and improve resistance to in- fection	Insomnia, nervousness, irritability	
Ephedrine (ma huang) <sup>1,52,54</sup>	Stimulant, appetite suppressant, treatment of asthma, colds, flu, nasal congestion	Seizures, high blood pressure, cardiac arrhythmia and infarc- tion, insomnia, psychosis, stroke, urine retention, uterine contractions	Metabolife (Metabolife International, Inc, San Diego, CA); Thermogenic Activator Plus (Rippedbody4less Corp, Marina Del Rey, CA); Ripped Fuel (Twinlab Inc, Ronkonkoma, NY).
Ginseng <sup>55</sup>	Stimulant	Sleeplessness, nervousness, hypertension, euphoria (GAS); hypertension together with nervousness, sleeplessness, skin eruptions, edema, morning diarrhea <sup>56,57</sup>	Metabolife
Khat <sup>58</sup>	Stimulant	Deterioration of psychosis, weight loss, abdominal pain	
Guarana <sup>58</sup>	Stimulant	Insomnia and agitation	Metabolife Thermogenic Activator Plus; Herbalife Products (Herbalife Inter- national Inc, Century City, CA); Diet Fuel (Twinlab)
Weight control			
Aristolochic acid <sup>26–28</sup>	Weight control	Interstitial renal fibrosis and re- nal failure	
Sauropus androgynus <sup>25</sup>	Weight control	Bronchiolitis obliterans	
Pain control/wound healing			
Comfrey <sup>4</sup>	Internal and external wound healing	Can cause carcinoma of the liver and veno-occlusive disease	
Feverfew <sup>1,52,53,59</sup>	Treatment of migraine head- aches, anti-inflammatory	Increases heart rate, allergic re- actions, mouth ulcers, head- aches, gastric disturbances, postfeverfew syndrome (with- drawal symptoms of aches, pains, and joint and muscle stiffness)	
Germander <sup>4,20,21</sup>	Choleretic and antiseptic properties	Causes hepatotoxicity; more than 30 cases of acute liver failure, including 1 fatality	
Anti-inflammatories			
Evening primrose oil <sup>59</sup>	Anti-inflammatory, sedative, anti- coagulant, astringent	Gastrointestinal disturbances	
Flax	Anti-inflammatory	Diarrhea, nausea, flatulence	
Lobelia <sup>1</sup>	Aid for asthma and bronchitis	Respiratory depression, rapid heart rate, coma, death	
Antidepressants			
St. John's wort <sup>1,52,53,59,60</sup>	Alleviates depression and anxiety	Restlessness, fatigue, photosen- sitivity, constipation, dizziness, dry mouth	
Sleep aids			
Kava kava <sup>1,60</sup>	Sedative, reduces stress	Gastrointestinal disturbance; temporary discoloration of skin, hair, and nails; metabolic abnormalities	
Valerian root <sup>1,52</sup>	Sleep aid	Decreases blood pressure, heart palpitations, upset stomach	

mon in the literature. 1,24,46,53,59,70,73–97 Adulteration cases often include Ayurvedic and Chinese herbal medicines with multiple ingredients; these products have been contaminated with lead, arsenic, and other highly toxic substances. The Brit-

ish National Poisons Information Service identified herbal preparations containing toxic levels of lead, zinc, mercury, arsenic, aluminum, and tin. The individuals who had ingested the herbals had blood concentrations of the heavy metals el-

Table 3. Potentially Beneficial Herbs

Herb Name	Safety/Efficacy*	Recommended Dosage <sup>10</sup>	Clinical Trials	
Chamomile (Matricaria chamomilla)	Safe and effective†4	Infusion/tea: 3 g/150 mL water steeped for 10 minutes	In controlled trials, positive effects on wound healing, as a mild sedative, and in combination with other herbs as a treatment for infant colic. <sup>59</sup>	
Echinacea (Echinacea)	Safe and effective†4	Varied; tincture: 30–60 drops, tid; pressed juice: 6–9 mL	Mixed results: beneficial in shortening duration of common colds but less effective in preventing colds. <sup>61-64</sup>	
Feverfew (Tanacetum parthenium)	Safe and effective‡9	50 mg-1.2 g/day (leaf powder)	Mixed results, but clinical research tends to support feverfew as a prophylaxis agent for migraines. 59,65	
Garlic (Allium sativum)	Safe and effective†4	Varied preparations; 4 g fresh gar- lic/day; 8 mg essential oil/day	Mild beneficial effect on serum lipids and reducing serum cholesterol, serum triglycerides, and low-density lipoprotein cholesterol; modest antihypertensive effect. Randomized, double-blind, placebo-controlled clinical trial: no change in cardiovascular risk factors compared with placebo in children who had familial hyperlipidemia. P	
Ginger (Zingiber officinale)	Safe and effective†4	2-4 g taken with liquid	Mixed results: treatment of motion sickness and postsurgical nausea and vomiting; helpful in treating hyperemesis gravidarum (morning sickness). 59,63	
Ginkgo biloba ( <i>Ginkgo</i> )	Safe and effective†4	120 mg dried extract bid to tid	Controlled trials: positive results in the treatment of chronic cerebral insufficiency.  Double-blind, placebo-controlled trials of patients who have memory loss: some improvement in memory. Randomized, controlled studies: promise in treating memory loss and psychopathologic conditions in Alzheimer disease and dementia. Controlled studies on intermittent claudication: favorable results. No studies have been done on pulmonary problems or attention deficit hyperactivity disorder. 59,63,66	
Ginseng (Panaxt ginseng)	Generally deemed safe and effective†4	Varied preparations, average daily dose is 1–2 g root/day	Clinical trials: ginseng improved mood, cog- nitive performance, and physical perfor- mance. <sup>67</sup>	
Saw palmetto (Serenoa repens)	Safe and effective†4	1–2 g/day	Randomized trials support the efficacy of saw palmetto in treating urinary flow in men with benign prostatic hyperplasia.89	
Valerian (Valeriana officinalis)	Safe and effective†4	Varied preparations; 15 g/day; tea: 3–5 g/150 mL hot water, steeped for 10–15 minutes, bid or tid	Randomized, double-blind, placebo-controlled studies: decreased sleep latency and improved sleep quality. <sup>59</sup>	

<sup>\*</sup>Standardization and product manufacturing practices vary greatly for the herbs listed. Although the herbs are potentially beneficial, poor standardization and product quality may alter the desired effect of the herbal product. †According to German Commission E.

evated by 2 to 10 times the upper limit of normal physiologic values.  $^{83}$ 

One report of herbal product adulteration showed more than 48 cases of renal poisoning when the patients thought they were taking fang ji. In actuality, patients were taking guang fang ji. The problem seems to lie in the similarity of the names in Chinese. To In another instance, a young woman suffering from lifelong eczema received an herbal cream from a Chinese practioner. She became suspicious after its effects resembled those of other corticosteroid creams she had used. She sent a sample to the Leicester Royal Infirmary for analysis and the presence of a corticosteroid, possibly fluocortolone or prednisolone, was confirmed. In yet another case, FDA researchers determined that a large batch of plant material laced with

digitalis was sold to several herbal companies in the US. Digitalis can cause nausea, vomiting, and irregular heartbeats.<sup>73</sup>

Many studies call into question the purity and content of herbal products. Bahrke and Morgan<sup>55</sup> reported on quantitative differences in individual and total ginsenosides within herbal products. The factors affecting these differences were species, growing environment, soil and fertility conditions, age of the roots, different parts of the plant, and extraction methods.<sup>98</sup> These aforementioned factors may also play a role in the physiologic effects of ginseng, which might explain the reported adverse effects.<sup>55</sup> Many of the problems associated with the adulteration, variable purity, and potency of herbs could be addressed with improved manufacturing and quality standards.

<sup>‡</sup>According to Health Protection Branch, Health and Welfare of Canada.

Table 4. Drug Interactions With Common Herbs

Drug Name	Common Use	Herbal Name	Common Use	Known Interactions
Anti-inflammatories				
Aspirin	Anti-inflammatory Analgesic Antipyretic Antirheumatic <sup>71</sup>	Ginkgo biloba	Increase circulation, increase short-term memory	Spontaneous hyphema <sup>70</sup>
Hydrocortisone	Anti-inflammatory	Licorice	Expectorant, antiulcer4	Glycyrrhetinic acid (an acid in topical anti-inflammatories) potentiates cutaneous vaso- constrictor response <sup>70</sup>
Oral and topical corticosteroids	Anti-inflammatory	Licorice	Expectorant, antiulcer <sup>4</sup>	Potentiates corticosteroids <sup>70</sup>
Oral contraceptives				
Combined oral contraceptive	Birth control	St. John's wort	Alleviate depression and anxiety	Breakthrough bleeding <sup>70</sup>
Oral contraceptives	Birth control	Licorice	Expectorant, antiulcer <sup>4</sup>	Hypertension, edema, hypoka- lemia <sup>70</sup>
Antidepressants				
Antidepressants	Antidepressant	Panax ginseng	Stimulant	Induces mania in depressed patients <sup>70</sup>
Lithium	Manic depression <sup>71</sup>	Psyllium	Reduce cholesterol <sup>72</sup>	Decreases lithium concentra- tions <sup>70</sup>
Paroxetine	Antidepressant <sup>71</sup>	St. John's wort	Alleviate depression and anxiety	Lethargy, incoherence <sup>70</sup>
Phenelzine	Monoamine oxidase in- hibitor; antidepres- sant <sup>71</sup>	Ginseng	Stimulant	Headache, tremor, mania <sup>70</sup>
Serotonin-reuptake inhibitors	Antidepressant	St. John's wort	Alleviate depression and anxiety	Mild serotonin syndrome, de- creased bioavailability of di- goxin, theophylline, cyclo- sporin, phenprocoumon <sup>70</sup>
Trazodone, sertraline, and mefazodone	Antidepressant; obsessive/compulsive disorders <sup>71</sup>	St. John's wort	Alleviate depression and anxiety	Mild serotonin syndrome <sup>70</sup>
Bronchodilator				
Theophylline	Bronchodilator <sup>71</sup>	St. John's wort	Alleviate depression and anxiety	Decreased theophylline concentration <sup>70</sup>

# **Product Manufacturing**

The DSHEA granted authority to the FDA to establish "good manufacturing practices" for herbal products. These regulations would govern the preparation, packing, and holding of dietary supplements under conditions that assure their safety. These regulations are to be modeled under guidelines currently in effect for the food industry. To date, the FDA has not fully implemented manufacturing guidelines for the herbal industry. 99

Good manufacturing practices to ensure purity and potency of products were a common theme during the June 1999 Dietary Supplement Stakeholder Meeting held by the FDA's Center for Food Safety and Applied Nutrition. This meeting included participants from every aspect of the herbal industry. At the center of the manufacturing discussion is the idea of standardization. Setting standards for supplements would mean that a specified amount of a herb is detectable, measurable, and known to have a biological response in the body. This desired consistency does not currently exist. Resolving this problem of standardizing and regulating herbal supplements is difficult. Differences in soil quality, percentage of herb utilized, harvest time, climate changes, growing seasons, and exposure to light are some factors that may affect herb quality.

While the need to improve manufacturing practices is widely accepted, lack of agreement on standards and rules for enforcement has slowed the bureaucratic rule-making process.<sup>99</sup>

The herbal industry has taken strides to police itself with regard to product quality. The National Nutritional Foods Association randomly tests products produced by its members. The Association also plans to begin certification of factories every 3 years using the same good manufacturing processes proposed by the FDA, although manufacturers are not obligated to belong to this organization. In addition to the National Nutritional Foods Association, the United States Phamacopeia (USP) sets standards for pharmaceuticals, vitamins, and minerals. The USP, a private, nonprofit organization, has begun to produce monographs about herbs that sum up evidence of effectiveness and detail standards for quality, strength, and purity of the final product. 1,99 Adoption of these standards is voluntary, and manufacturers claiming to meet them are not checked except in response to complaints.

# **CONCLUSIONS**

Despite the increased tendency to seek natural therapies, athletes need to be aware that "natural" does not equal

"safe." Herbs should not be touted as miraculous cure-alls but rather compounds that work through simple biochemistry. Specific compounds trigger a specific physiologic effect—an effect that can be exacerbated if too much of a product is used or if it is used in combination with other medications. Athletes are entitled to know that most herbs are not proven safe and effective under current FDA standards. In addition, athletes may be unaware that the hyperbolic advertising and advocacy literature surrounding herbal products often contains untested claims. If an athlete wishes to take an herbal supplement, he or she should use a standardized product. Products should have the scientific name and quantity of the botanical clearly identified on the label. The name and address of the manufacturer, lot number, and expiration date should be clearly marked.<sup>4</sup>

Given the risks of toxicity and drug interaction, questions regarding the use of herbal supplements are essential when a health care provider takes a complete history. Athletes should consult a physician about potential drug interactions (both over the counter and prescription) before taking an herbal supplement. They should be advised to stop taking the herb immediately if adverse effects occur. Athletic trainers and physicians must be aware that herb use is deeply rooted in specific cultures and a key component of folk medicine. Therefore, an appropriate level of cultural sensitivity must be used when discussing the use of these products with athletes. Being judgmental or dismissive when discussing herbal products can erode the athlete's trust. The sports medicine team must be able to provide honest, unbiased information to educate athletes regarding herbal supplements.

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